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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,606

06/03/2005

Masato Yoshioka

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3568

2292 7590 09/22/2008  
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EXAMINER

FISHER, ABIGAIL L

ART UNIT

PAPER NUMBER

1616

NOTIFICATION DATE

DELIVERY MODE

09/22/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/537,606	<b>Applicant(s)</b> YOSHIOKA ET AL.	
	<b>Examiner</b> ABIGAIL FISHER	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt of Amendments and Remarks filed on June 30 2008 is acknowledged.

Claims 1, 6, and 8 were amended. Claims 1-8 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

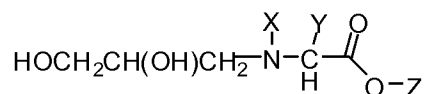
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carrell et al. (US Patent No. 5514808).**

**Applicant Claims**

The instant application claims a composition comprising an amino acid N-glyceryl derivative that has the following formula (formula I):



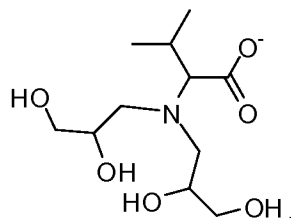
where in X is a hydrogen,  $\text{CH}_2\text{CH}(\text{OH})\text{CH}_2\text{OH}$  group, or an alkyl group having 1 to 4 carbons; Y is a side chain of basic or neutral  $\alpha$ -amino acids; and Z is a hydrogen, alkali metal, ammonium group, organic ammonium group or  $\text{CH}_2\text{CH}(\text{OH})\text{CH}_2\text{OH}$ .

**Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

Carrell et al. is directed to hydroxyl ions as unique therapeutic agents. The compounds of the invention have the formula (column 4):



One exemplified compound (example 8) is 2-[N,N-bis-(2,3-dihydroxypropyl)amino]isovalerate which has the following formula:



This corresponds to  $X = \text{CH}_2\text{CH}(\text{OH})\text{CH}_2\text{OH}$ , Y is a side chain of valine and Z is a H or salt thereof such as lithium, potassium tetramethylammonium, etc. for the instant claimed formula.

Other compounds that are listed that particularly useful for the  $R^2$  include H (which corresponds to glycine),  $\text{CH}_3$  (alanine),  $\text{NH}(\text{CH}_2)_3$  (ornithine),  $\text{H}_2\text{NCOCH}_2\text{CH}_2$  (glutamine), as well as side chains corresponding to lysine, isoleucine, methionine, tryptophan, and valine (columns 8-9, lines 49-65 and 1-20).

It is taught that the compositions can be utilized to prove a dermal therapeutic effect (column 11, lines 58-67) and topical therapeutic effects (column 5, line 14). Formulations include ointments and creams (example 12). Exemplified amounts of the hydroxyl ion modulating compounds are from 1 to 15% of the total mixture (example 12)

**Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)**

Carrell et al. do not exemplify ointment or cream formulations comprising the exemplified isovalerate. Carrell et al. do not exemplify hydroxyl ion modulating compounds wherein  $R_2$  is a basic amino acid side chain. However, Carrell et al. do teach that the compounds can be utilized in ointment or cream formulations and indicate that preferred moieties for  $R_2$  include basic moieties such as lysine and ornithine.

***Finding of Prima Facie Obviousness Rational and Motivation*  
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art to formulate the exemplified 2-[N,N-bis-(2,3-dihydroxypropyl)amino]isovalerate compound in a topical ointment or cream formulation. One of ordinary skill in the art would have been

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motivated to formulate a ointment or cream with this compound as it is one hydroxyl ion modulating compound exemplified and Carrell et al. teach that these compounds can be utilized in topical therapeutic formulations.

It would have been obvious to one of ordinary skill in the art to formulate hydroxyl ion modulating compounds in which the R<sub>2</sub> moiety is a basic amino acid such as lysine or ornithine. One of ordinary skill in the art would have been motivated to substitute the exemplified valine moiety for lysine or ornithine as they are taught by Carrell et al. as functional equivalents.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Regarding the preambles of claims 1 and 4-5, the recitation of cosmetic, skin care cosmetic, and hair cosmetic have not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

***Response to Arguments***

Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher  
Examiner  
Art Unit 1616

AF

/Mina Haghighatian/  
Primary Examiner, Art Unit 1616